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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/600,358	09/25/00	ROIFMAN C	3477-88

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BERESKIN & PARR
BOX 401, 40 KING STREET WEST
M5H 3Y2 TORONTO, ONTARIO
CANADA

AIR MAIL

EXAMINER	
WHITEMAN, B	
ART UNIT	**PAPER NUMBER**
1633	10

DATE MAILED: 09/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/600,358	Applicant(s) ROIFMAN, CHAIM M.	
	Examiner Brian Whiteman	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-39 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 1-39 are pending in instant application

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-22, 27, 30(b), 31, 32, and 33(a, b), drawn to an isolated polynucleotide comprising a nucleotide sequence encoding a Lyp protein (SEQ ID NO: 2); The polynucleotide of claim 3, wherein the nucleotide sequence is selected from the group consisting of (a) a nucleotide sequence encoding the amino acid sequence of table 2 (SEQ ID NO: 2) or a splice variant thereof; S recombinant vector comprising a polynucleotide encoding SEQ ID NO: 2; A substantially purified Lyp protein encoding SEQ ID NO: 2; The protein of claim 13 wherein the protein comprises an amino acid sequence selected from (a) the amino acid sequence of Table 2 (SEQ ID NO: 2); a non-human animal wherein a genome of said animal, has been modified by an insertion of a polynucleotide encoding a heterologous Lyp gene (SEQ ID NO: 1 or DNA encoding SEQ ID NO: 2).

Group II, claim(s) 1-22, 27, 30(b), 31, 32, and 33(a, b), drawn to an isolated polynucleotide comprising a nucleotide sequence encoding a Lyp protein (SEQ ID NO: 4); the polynucleotide of claim 3, wherein the nucleotide sequence is selected from the group consisting of (a) a nucleotide sequence encoding the amino acid sequence of table 4 (SEQ ID NO: 4) or a splice variant

thereof; a recombinant vector comprising a polynucleotide of claim 1; A substantially purified Lyp protein encoding SEQ ID NO: 4; The protein of claim 13 wherein the protein comprises an amino acid sequence selected from (a) the amino acid sequence of Table 4 (SEQ ID NO: 4); a non-human animal wherein a genome of said animal, has been modified by an insertion of a polynucleotide encoding a heterologous Lyp gene (SEQ ID NO: 3 or DNA encoding SEQ ID NO: 4).

Group III, claim(s) 23-26 and 33(c), drawn to an antibody, which binds specifically to a Lyp protein.

Group IV, claim(s) 28, drawn to a method for screening a candidate compound for ability to increase or decrease the phosphatase activity of a Lyp protein.

Group V, claim(s) 29, drawn to a method for screening a candidate compound for ability to modulate expression of a Lyp gene.

Group VI, claim 30a, drawn to a non-human animal wherein a genome of said animal has been modified by a modification selected from the group consisting of knockout of a Lyp1 gene (SEQ ID NO: 1).

Group VII, claim 30a, drawn to a non-human animal wherein a genome of said animal has been modified by a modification selected from the group consisting of knockout of a Lyp2 gene, SEQ ID NO: 3.

Group VIII, claim(s) 34(a), drawn to a method for treating a subject having a deficiency of Lyp activity comprising administering an isolated nucleotide sequence encoding a Lyp protein.

Group IX, claim(s) 34(b), drawn to a method for treating a subject having a deficiency of Lyp activity comprising administering a substantially purified Lyp protein.

Group X, claim(s) 35, 36, and 39, drawn to a method for modulating signaling mediated by the T cell receptor.

Group XI, claim(s) 37, drawn to a method for treating a disorder, which requires immunosuppression, the method comprising administering to the subject an immunosuppression effective amount of an agent which increases Lyp phosphotase.

Group XII, claim(s) 38, drawn to a method for treating lymphoma in a subject.

Group XIII, claim(s) 39, drawn to a method for preventing or treating a disorder characterized by an abnormality in the IL2-mediated signaling pathway.

The inventions listed as Groups I-XIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT rule 13.2, they lack the same or corresponding special features for the following reasons:

37 CFR 1.475(c) states:

"If an application contains claims to more or less than one of the combination of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present."

37 CFR 1.475(d) also states:

"If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c)."

37 CFR 1.475(e) further states:

"The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternative within a single claim."

In view of 37 CFR 1.475 (c), 37 CFR 1.475 (d), and 37 CFR 1.475 (e). Group I is considered the main invention to the product first mentioned in the claims (claim 1), and the first recited invention drawn to other categories related thereto, e.g. a method of making (claim 27), method of use (claim 30b).

Groups I, II, III, VI, and VII are drawn to multiple distinct products that do not share the same inventive concept. The claimed invention of Groups II, III, VI, and VII recite distinct materials that are neither require nor recited in the claimed invention of Group I, and thus have their own special technical features. For example, the nucleic acid (SEQ ID NO: 3 or the DNA encoding the amino acid set forth in SEQ ID NO: 4) as claimed in Group II; antibody as claimed in Group III; a genetically modified non-human animal missing the Lyp1 gene as claimed in Group VI, and a genetically modified non-human animal missing the Lyp2 gene in Group VII encompass structural materials that are distinct than the sequences of Group I. Thus, it follows from the preceding analysis that the claimed inventions listed as Group I and Groups II-XIII do not related to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2 they lack the same or corresponding special technical feature for the reasons set forth above.

In addition, the claimed inventions of Group I-XIII recite distinct materials and/or methods steps that are neither required nor recited in the claimed invention of Group I, and thus lack the same or corresponding technical feature for the following reasons:

The special technical feature of Group I is considered to be an isolated polynucleotide encoding SEQ ID NO: 1 (Lyp1).

The special technical feature of Group II is considered to be an isolated nucleic acid sequence (Lyp2) encoding for SEQ ID NO: 3.

The special technical feature of Group III is considered to be an antibody.

The special technical feature of Group IV is considered to be a method for screening a candidate compound for ability to increase or decrease the phosphatase activity of a Lyp protein.

The special technical feature of Group V is considered to be a method for screening a candidate compound for ability to modulate expression of a Lyp gene.

The special technical feature of Group VI is considered to be a knock out non-human animal wherein the genome of said animal is missing Lyp1 gene (SEQ ID NO: 1).

The special technical feature of Group VII is considered to be a knock out non-human animal wherein the genome of said animal is missing Lyp2 gene (SEQ ID NO: 3).

The special technical feature of Group VIII is considered to be a method for treating a subject having a deficiency of Lyp activity comprising administering an isolated nucleotide sequence encoding a Lyp protein.

The special technical feature of Group IX is considered to be a method for treating a subject having a deficiency of Lyp activity comprising administering a substantially purified Lyp protein.

The special technical feature of Group X is considered to be a method for modulating signaling mediated by the T cell receptor.

The special technical feature of Group XI is considered to be a method for treating a disorder, which requires immunosuppression, the method comprising administering to the subject an immunosuppression effective amount of an agent which increases Lyp phosphotase.

The special technical feature of Group XII is considered to be a method for treating lymphoma in a subject.

The special technical feature of Group XIII is considered to be a method for preventing or treating a disorder characterized by an abnormality in the IL-2 mediated signaling pathway.

Accordingly Groups I-XIII are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

The inventions listed as Groups I-XIII do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the reasons set forth above.

As the technical feature linking the members of the listed in claim does not constitute a special feature as defined by PCT Rule 13.2, particularly since the compound(s) and/or substance(s) listed in the claims do not share a structural feature in common with respect to their site of action. Thus, the requirement of unity of the invention is not fulfilled.

The nucleotide sequences of Inventions I-II are distinct because the nucleotide sequences do not appear to share a common structure. "The significance of the alternative C-terminal sequences of Lyp1 and Lyp2 remains unclear, but there are several differences between the C-terminal tails that may be key in revealing functional divergence (Applicants' specification, page 12)". Furthermore, "the final 123 amino acids of Lyp1 are absent in Lyp2 and replaced by seven unique residues (page 11)." Therefore, it would be an undue burden on the examiner to search

all the nucleotide sequences, since each sequence encodes a distinct functional polypeptide from different species and the USPTO resources are stretched to the limit. Thus, only one patentably distinct nucleotide sequence thereof can be searched per application.

Because these inventions are distinct for the reasons given above and the literature search required for Group I is not required for Groups II-XIII, restriction for examination purposes as indicated is proper.

Thus it would be unduly burdensome for the examiner to search all of the claimed inventions being sought in the pending claims.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Tracey Johnson whose telephone number is (703) 305-2982.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on M-F, (730-400 EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Clark can be reached at (703) 305-4051.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Dave

DAVE T. NGUYEN
PRIMARY EXAMINER

Brian Whiteman
Patent Examiner, Group 1633
September 27, 2001